CLAIMS

What is claimed is:

Sub E1

1. A method for estimating length of survival of a cancer patient, said method comprising:

(a) obtaining a biological sample from a cancer patient having at least a preliminary diagnosis of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a breast cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, a adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma;

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level in normal healthy humans wherein a sample YKL-40 level in excess of YKL-40 levels in normal healthy humans indicates a reduced survival expectancy compared to patients with normal YKL-40 level.

2. The method of claim 1, wherein said patient has a diagnosis of prostate cancer.

3. The method of claim 1, wherein said patient has a diagnosis of lung cancer.

4. The method of claim 1, wherein said patient has a diagnosis of a colorectal cancer.

5. The method of claim 4, wherein said patient is diagnosed with a Duke's stage A colorectal cancer.

6. The method of claim 4, wherein said patient is diagnosed with a Duke's stage B colorectal cancer.

7. The method of claim 4, wherein said patient is diagnosed with a Duke's stage C colorectal cancer.

8. The method of claim 4, wherein said patient is diagnosed with a Duke's stage D colorectal cancer.

9. The method of claim 1, wherein said biological sample is a primar tumor or a tissue affected by the cancer.

10. The method of claim 1, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, or tumor tissue.

11. The method of claim 1, wherein the level of YKL-40 is measured by immunohistochemical staining of cells comprising said biological sample.

12. The method of claim 11, wherein said cells are tumor tissue cells.

13. The method of claim 1, wherein the level of YKL-40 is measured using an immunoassay.

14. The method of claim 13, wherein said immunoassay is a competitive immunoassay.

15. The method of claim 13, wherein said immunoassay is an ELISA.

16. The method of claim 13, wherein said immunoassay is a radioimmunoassay (RIA).

17. The method of claim 13, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

18. The method of claim 13, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

19. A method of treating a cancer in a patient, said method comprising:

(a) obtaining a biological sample from a cancer patient having at least a preliminary diagnosis of a cancer;

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level in normal healthy humans wherein a sample YKL-

40 level in excess of YKL-40 levels in normal healthy humans indicates a reduced survival expectancy compared to patients with normal YKL-40 level; and

(c) selecting a patient identified with a YKL-40 level excess of YKL-40 levels in normal healthy humans and providing an adjuvant cancer therapy selected from the group consisting of chemotherapy, radiation therapy, reoperation, antihormone therapy, and immunotherapy.

20. The method of claim 19, wherein said patient has a diagnosis of a cancer selected from the group consisting of colorectal cancer, lung cancer, prostate cancer;

21. The method of claim 20, wherein said patient has a diagnosis of prostate cancer.

22. The method of claim 20, wherein said patient has a diagnosis of lung cancer.

23. The method of claim 20, wherein said patient has a diagnosis of colorectal cancer.

24. The method of claim 23, wherein said patient is diagnosed with a Duke's stage A colorectal cancer.

25. The method of claim 23, wherein said patient is diagnosed with a Duke's stage B colorectal cancer.

26. The method of claim 23 wherein said patient is diagnosed with a Duke's stage C cancer.

27. The method of claim 23, wherein said patient is diagnosed with a Duke's stage D colorectal cancer.

28. The method of claim 19, wherein said biological sample is a primary tumor or a non-primary tumor tissue affected by the cancer.

29. The method of claim 19, wherein said biological sample is a sample of whole blood, plasma, serum , synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, or tumor tissue.

30. The method of claim 1, wherein the level of YKL-40 is measured by immunohistochemical staining of cells comprising said biological sample.

31. The method of claim 30, wherein said cells are tumor tissue cells.

32. The method of claim 19, wherein the level of YKL-40 is measured using an immunoassay.

33. The method of claim 19, wherein said immunoassay is a competitive immunoassay.

34. The method of claim 19, wherein said immunoassay is an ELISA.

35. The method of claim 19, wherein said immunoassay is a radioimmunoassay (RIA).

36. The method of claim 32, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

37. The method of claim 32, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

38. A method to screen for recurrence of a cancer after removal of a primary tumor, said method comprising::

(a) obtaining a biological sample from a cancer patient following removal of a primary tumor; and

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level in normal healthy humans wherein a sample YKL-40 level in excess of YKL-40 levels in normal healthy humans indicates a possible recurrence of said cancer.

39. The method of claim 38, wherein said method is repeated at a multiplicity of instances after removal of said primary tumor.

40. A method of monitoring effectiveness of cancer treatment in patients with elevated YKL-40, said method comprising:

(a) obtaining a first biological sample from a cancer patient following having elevated levels of YKL-40 as compared the YKL-40 level in normal healthy humans;

(b) providing one or more treatments of said cancer;

(c) obtaining a second biological sample from said cancer patient during or after said one or more treatments; and

(d) measuring a level of YKL-40 in said second biological sample and comparing the level of YKL-40 in said second sample to the level of YKL-40 in said first sample, wherein a lower level of YKL-40 in said second sample as compared to the YKL-40 level in said first sample indicates efficacy of said one or more treatments.

41. The method of claim 40, wherein said one or more treatments are selected from the group consisting of chemotherapy, radiation therapy, immunotherapy, anti hormone therapy, and surgery.

42. A method of monitoring effectiveness of treatment of a primary tumor in a patient with elevated YKL-40 prior to surgery or to other treatments designed to eliminate the cancer, said method comprising:

(a) obtaining a first biological sample from said patient following surgery to remove said primary tumor or other treatment; and

(b) measuring a level of YKL-40 in said biological sample and comparing the level of YKL-40 in said sample to:

1) the level of YKL-40 in a in a normal healthy human; or

2) the level of YKL-40 in a biological sample obtained from said patient prior to, during, or immediately after said surgery or other treatment;

wherein a YKL-40 level in said first biological sample comparable to said second biological sample indicates a lack of efficacy of said surgery or other treatment and a YLK-40 level in said first sample significantly above the YKL-40 level in normal healthy humans indicates a limited efficacy of said surgery or other treatment.

43. A method of detecting a bacterial infection of a mammal resulting in leukocyte proliferation, said method comprising:

(a) obtaining a biological sample from said mammal;

(b) measuring a level of YKL-40 in said sample and comparing the level to the YKL-40 level found to that found in a normal healthy mammal, wherein a

statistically significant difference in YKL-40 levels indicates the presence of a bacterial infection.

44. The method of claim 43, wherein said bacterial infection is selected from the group consisting of bacterial pneumonia, and meningitis.

45. A method of detecting a disease characterized by macrophage activation, said method comprising:

(a) obtaining a biological sample from said mammal;

(b) measuring a level of YKL-40 in said sample and comparing the level to the YKL-40 level found to that found in a normal healthy mammal, wherein a statistically significant difference in YKL-40 levels indicates the presence of a disease characterized by macrophage activation..

46. The method of claim 45, wherein said bacterial infection is selected from the group consisting of giant cell arteritis.

47. A method of screening for a cancer, in a mammal, said method comprising:

(a) obtaining a biological sample from said mammal;

(b) measuring a level of YKL-40 in said sample and comparing the level to the YKL-40 level found in that of a normal healthy mammal, wherein a statistically significant difference in YKL-40 levels indicates the presence of a cancer.

48. The method of claim 47, wherein said biological sample is a tissue affected by the cancer.

49. The method of claim 47, wherein said biological sample is a sample of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, or tumor tissue.

50. The method of claim 47, wherein said cancer is selected from the group consisting of a breast cancer, a colon cancer, a lung cancer, a prostate cancer.

51. The method of claim 47, wherein said cancer is selected from the group consisting of a stomach cancer, a cervical cancer, and ovarian cancer, and a malignant melanoma.

52. The method of claim 50, wherein said cancer is a breast cancer.

~~53. The method of claim 50, wherein said cancer is a colon cancer.~~

54. The method of claim 50, wherein said cancer is a prostate cancer.

55. The method of claim 50, wherein said cancer is a lung cancer.

56. The method of claim 47, wherein said mammal is a human.

57. The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

58. The method of claim 57, wherein said immunoassay is a competitive immunoassay.

59. The method of claim 57, wherein said immunoassay is an ELISA.

60. The method of claim 57, wherein said immunoassay is a radioimmunoassay (RIA).

61. The method of claim 57, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

62. The method of claim 57, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.